REMARKS

Claims 24 through 49 are pending is this application. Claims 35-46 have been widthdrawn as directed to a non-elected species and new claims 47-49 have been added, leaving claims 24-34 and 47-49 for examination. New claims 47 through 49 further define the stent as configured for a gastric approach and particularly for treating a pseudocyst. In particular, new claim 47 recites "the self-expanding stent is adapted to drain a gastric pseudocyst when implanted," and new claim 48 recites "the self-expanding stent has a diameter when expanded that is larger than a diameter of an endobiliary tube." New dependent claim 49 recites "the self-expanding stent has an expanded diameter of greater than about 8 mm." Support for these amendments can be found throughout the specification and drawings, including, for example, at paragraph 51 of the published application. No new matter has been added.

Information Disclosure Statement

The Office Action of December 7, 2006 ("Office Action") objects to the information disclosure statement of 09/15/03 for failing to provide a copy of each cited non-patent literature document or that portion which caused it to be listed. Each of the cited non-patent literature documents was previously submitted to the Patent and Trademark Office in a related application; Application Serial No. 09/843,449, now Patent No. 6,620,122. Thus, under Rule 1.98(d), a copy of each such document is not required to be filed. However, if the documents are not available or not present in the file wrapper of the related application, Applicants will provide copies at the Examiner's request.

§102(e) Rejections

The present '570 Application is generally directed, for example, to methods and devices for draining pseudocysts. Pseudocysts can occur within the abdominal cavity or peritoneal cavity as a result of a build up of tissue, fluid, debris, pancreatic enzymes and/or blood. In one aspect, the '570 Application describes a stent delivery system for implanting a stent within the gastric or abdominal wall to facilitate draining of a pseudocyst. The stent can be a self-expandable stent adapted to drain a gastric pseudocyst when implanted and having a diameter when expanded that is larger than the diameter of an individual endobiliary tube. As described in the '570 application, endobiliary tubes were previously used to drain pseudocysts, but had certain drawbacks including the need to implant multiple endobiliary tubes and the tendency of the tubes to become blocked or partially obstructed.

A. The Gambale Reference

The Examiner rejects claims 24-28, 30, 31, and 33 pursuant to 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,458,092 to Gambale et al. ("Gambale"). In particular, with respect to independent claim 24, the Office Action states that:

> Gambale discloses a stent delivery system comprising: an inner catheter (80) with a first lumen; perforating means (82,84) slidably disposed in the first lumen; an outer catheter (36) adapted for axial movement relative to the inner catheter; a self expandable stent (70) disposed between the inner and outer catheter.

Office Action at p. 3.

Applicants respectfully traverse this rejection because Gambale fails to suggest or disclose a stent positioned between an inner and outer catheter.

The Gambale reference is directed to angiogenesis implant devices that are implanted into cardiac tissue to foster the growth of blood vessels. The implants

expand when implanted and irritate and slightly injure the surrounding tissue to provoke an injury response that results in angiogenesis. The flow of blood from the surrounding tissue into the implant and pooling of the blood in and around the implant leads to thrombosis and fibrin growth. The healing process leads to angiogenesis in the tissue surrounding the implant.

Unlike Gambale, the present '570 Application claims an inner catheter having a first longitudinally extending lumen, perforating means slidably disposed in said first longitudinally extending lumen, and an outer catheter surrounding at least a portion of the length of the inner catheter and adapted for axial movement relative to the inner catheter. In addition, claim 24 requires a self-expandable stent disposed between the inner catheter and outer catheter.

Gambale fails to disclose such a system, particularly a stent positioned between inner and outer catheters. The Office Action points to push tube 80 as corresponding to the claimed inner catheter, delivery catheter 36 as corresponding to the claimed outer catheter, and rolled tube 70 as corresponding to the claimed stent. FIGS. 9A and 9C, reproduced below, illustrate these elements.

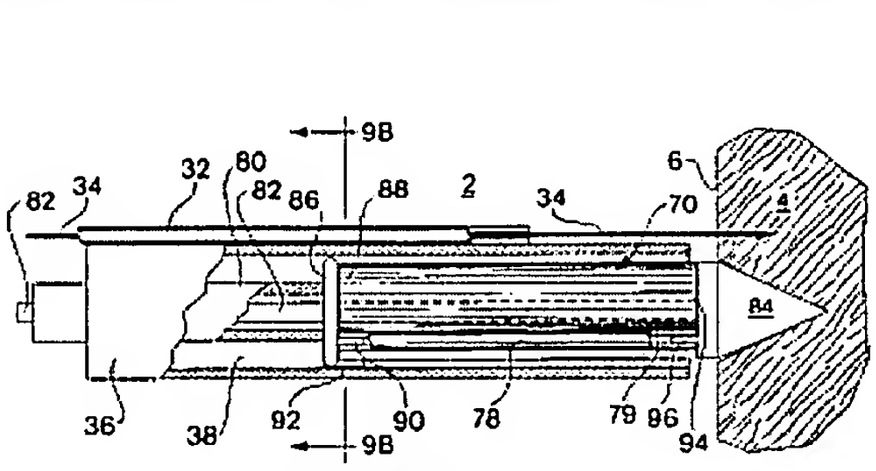

Fig. 9A

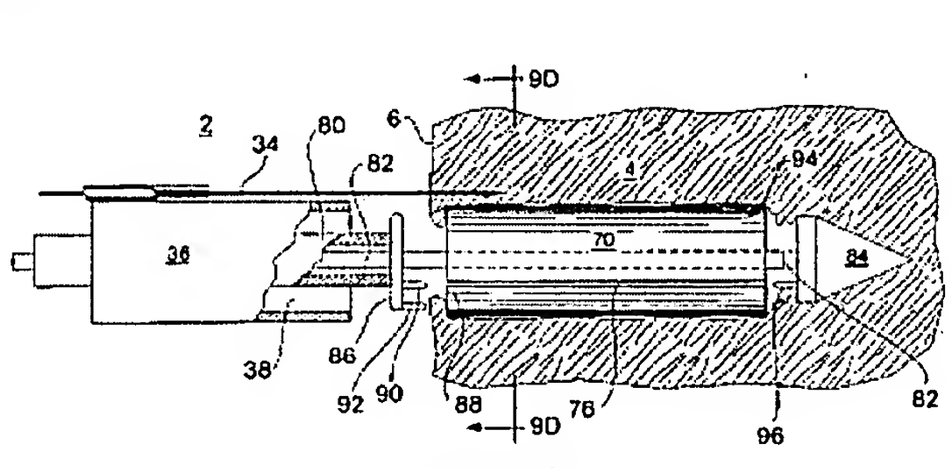

Fig. 9C

As shown, the rolled tube (70) is not positioned *between* the push tube (80) and the delivery catheter (36). Instead, the rolled tube (70) is positioned adjacent to the distal

end of the push tube so that the push tube can "push" the stent out of the distal end of catheter (36).

The rolled tube of Gambale, because of its "rolled" configuration and large diameter, cannot be positioned between the push tube (80) and the catheter (36). As show in FIG. 9B, reproduced below, the rolled tube, when rolled, occupies most of the inner volume of catheter 36 and would prevent the placement of the catheter (36) in the claimed configuration.

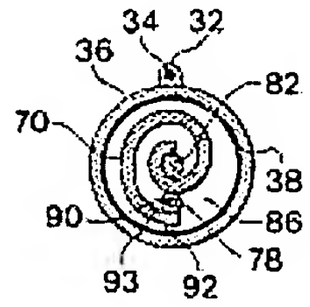

Fig. 9B

With respect to the new dependent claims 47 through 49, Gambale also fails to teach or disclose a self-expanding stent adapted to drain a gastric pseudocyst when implanted. Moreover, the implants of Gambale do not correspond to a self-expanding stent adapted to drain a gastric pseudocyst when implanted and having a diameter when expanded that is larger than the diameter of an individual endobiliary tube. The disclosure of Gambale also does not teach or suggest a self-expanding gastric stent that has an expanded diameter of greater than about 8 mm.

The implants of Gambale are not configured for delivery via a trans-oral approach or for implantation into a gastric or abdominal wall for treating a pseudocyst. Instead, Gambale's implants are implanted in cardiac tissue, particularly the myocardium of the heart. Instead of permitting drainage, Gambale's implants intentionally cause tissue injury to promote vascularization and blood vessel growth.

Moreover, Gambale states that the implants should have a small profile; 1.0 to 1.5 mm to facilitate tissue penetration. Col. 8, line 51-53. Once positioned, the implants expand to a size of 2.0 to 2.5 mm to cause tissue irritation and injury. Col. 8, ll. 59-64. Such implants differ substantially from the pseudocyst draining stent required by claims 47, 48, and 49.

One skilled in the art, after reviewing the disclosure of Gambale, would have no reason to reconfigure the implants of Gambale to meet the limitations of claims 47 through 49. In particular, one skilled in the art would have no reason to change the dimensions of Gambale's implants because Gambale's implants are specifically configured for cardiac applications. Using an implant larger than that disclosed by Gambale could possibly cause unwanted tissue damage in a sensitive and vital organ; the heart. Moreover, Gambale's focus on *small* implants to produce *minimal injury* teaches away from scaling the implants to a size that could permit pseudocyst drainage. Instead, the implants described in Gambale are sized much closer to conventional endobiliary tubes.

One skilled in the art would not consider Gambale relevant when looking for solutions to treating a gastric pseudocyst. Gambale's implants are particularly suited for cardiac applications and causing blood vessel growth. Even if considered relevant, Gambale teaches away from increasing the size of the implants because Gambale's implants are adapted for a particular use, namely angiogenesis. Larger implants would be at odds with the purpose (angiogenesis) and intended use (cardiac) of the Gambale reference. Moreover, one skilled in the art would have no reason, aside from hindsight, to choose a larger device for draining pseudocysts because conventional treatments

use much smaller devices. If anything, one skilled in the art would select implants having the same size as Gambale because the implants of Gambale correspond in size to conventional endobiliary tubes.

The Gambale reference fails to teach or disclose the system of claim 24. In particular, Gambale lacks a stent positioned between an inner and outer catheter. Moreover, with respect to dependent claim 47, Gambale lacks a self-expanding stent adapted to drain a gastric pseudocyst when implanted. In addition, the disclosure of Gambale is at odds with a gastric stent having a diameter when expanded that is larger than the diameter of an individual endobiliary tube or greater than about 8 mm. Accordingly, Applicants respectfully submit that the rejection of independent claim 24, and the claims dependent thereon, should be withdrawn.

B. The Phelps Reference

The Examiner rejects claims 24, 25, 29-31, and 33 pursuant to 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,290,728 to Phelps et al. ("Phelps"). In particular, with respect to independent claim 24, the Office Action states that:

> Phelps discloses a stent delivery system comprising: an inner catheter (22) with a first lumen; perforating means (16) slidably disposed in the first lumen; an outer catheter (26) adapted for axial movement relative to the inner catheter; a self expandable stent (20) disposed between the inner and outer catheter.

Office Action at p. 3.

Applicants respectfully traverse this rejection because Phelps fails to suggest or disclose an outer catheter adapted for axial movement relative to the inner catheter. and with respect to new claims 47 through 49, Phelps fails to suggest or disclose (1) a self-expanding stent adapted to drain a gastric pseudocyst when implanted, (2) a self-expanding stent adapted to drain a gastric pseudocyst when implanted and having a

diameter when expanded that is larger than the diameter of an individual endobiliary tube, or (3) a self-expanding stent adapted to drain a gastric pseudocyst when implanted and having an expanded diameter greater than about 8 mm.

The Phelps reference is directed to a method for creating a conduit in the myocardium or heart wall to permit passage of blood flow between the left ventricle and the coronary artery. In one aspect, the conduit is provided by a cardiac stent that is implanted in cardiac tissue. Phelps does not mention abdominal applications or the treatment of gastric pseudocysts.

Conversely, claim 24 of the present '570 Application recites an inner catheter having a first longitudinally extending lumen, perforating means slidably disposed in said first longitudinally extending lumen, and an outer catheter surrounding at least a portion of the length of the inner catheter and adapted for axial movement relative to the inner catheter. In addition, claim 24 requires a self-expandable stent disposed between the inner catheter and said outer catheter.

Phelps fails to disclose the claimed system, particularly an outer catheter configured to move axially with respect to an inner catheter. The Office Action points to catheter 22 as corresponding to the claimed inner catheter and retaining sheath 26 as corresponding to the claimed outer catheter. According to the disclosure of Phelps, the retaining sheath is "withdrawn" to allow a cardiac stent (20) to expand and to open a conduit from the ventricle to the coronary artery. Col. 6, ll. 24-26. Nowhere does Phelps suggest relative "axial" movement as the mechanism for "withdrawing." In fact, Phelps fails to disclose any mechanism for movement of "retaining sheath 26" relative to other

elements of Phelps's system. Accordingly, Phelps lacks at least one required element of independent claim 24.

In addition, with respect to dependent claims 47 though 49, the cardiac stent of Phelps does not correspond to a self-expanding stent adapted to drain a gastric pseudocyst when implanted. Moreover, the cardiac stent of Phelps does not have a diameter when expanded that is larger than a diameter of an individual endobiliary tube or an expanded diameter of about 8 mm. The cardiac stent of Phelps is not configured for delivery via a trans-oral approach or for implantation into a gastric or abdominal wall for treating a pseudocyst. Instead, Phelps's stent is implanted in cardiac tissue, particularly the myocardium of the heart. Thus, the stent of Phelps is configured for implanting within muscle or thick tissue of the heart rather than providing a port through an anatomical wall such as the gastric or abdominal wall.

Given the cardiac application of Phelps, the stent of Phelps would have a size, particularly a diameter, much smaller than the pseudocyst draining stent of the '570 application. At most, the cardiac stent of Phelps would have a diameter approximate to that of the coronary artery because the cardiac stent of Phelps provides a replacement pathway for the coronary artery. Typically, the coronary artery has a diameter of 2.5 to 3.5 mm, which is far smaller than the pseudocyst draining stent of claim 48 and the claimed expanded diameter of greater than about 8 mm required by dependent claim 49.

One skilled in the art, after reviewing the disclosure of Phelps, would have no reason to reconfigure the cardiac stent of Phelps to permit drainage of a pseudocyst. In particular, one skilled in the art would have no reason to change the dimensions of

Phelps's stent because Phelps's implant, like those of Gambale discussed above, are specifically configured for cardiac applications. Using a stent larger than that disclosed by Phelps could possibly cause unwanted tissue damage to the heart.

One skilled in the art would not consider Phelps relevant when looking for solutions to treating pseudocysts. Phelps's implants are particularly suited for cardiac applications and treating a blocked coronary artery. Even if considered relevant, Phelps teaches away from increasing the size of the implants because Phelps's cardiac stent is adapted for a particular use, namely treating a blocked coronary artery. Larger implants would not suit such a purpose.

Moreover, even if one were to look to Phelps when considering treatment of pseudocyst, one skilled in the art would have no reason to choose a larger device for draining pseudocysts because conventional treatments use much smaller devices than the claimed stent. If anything, one skilled in the art would select stents having the same size as Phelps because the stents of Phelps correspond in size to conventional endobiliary tubes.

The Phelps reference fails to teach or disclose the system of claim 24. In particular, Phelps lacks an outer catheter adapted for axial movement relative to an inner catheter. Moreover, with respect to dependent claim 47, Phelps lacks a self-expanding stent adapted to drain a gastric pseudocyst when implanted. Still further, with respect to dependent claim 48, Phelps does not teach or disclose a stent having a diameter when expanded that is larger than a diameter of an individual endobiliary tube, or with respect to dependent claim 49, an expanded diameter of greater than about 8

mm. Accordingly, Applicants respectfully submit that the rejection of independent claim 24, and the claims dependent thereon, should be withdrawn.

§103(a) Rejections

The Examiner rejects claims 24, 25, 27, 30, 33, and 34 pursuant to 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,599,315 to Wilson in view of U.S. Patent No. 6,533,753 to Haarstad et al. ("Haarstad"), and further in view of Phelps. In particular the Office Action states that:

> Wilson discloses a stent delivery system comprising: an inner catheter (120) with a first lumen (125) with a guide wire (150) slidable disposed in the first lumen; a second lumen (126) with a guidewire (151) slidably disposed in the second lumen; and a self expandable stent (20) (Col 6, line 62) coaxially disposed over the inner catheter.
> ...
> Wilson in view of Haarstad does not disclose an outer catheter.
>
> Phelps discloses that it is well know to use a sheath (outer catheter) to restrain a self-expanding stent to hold the stent in a non-expanded configuration.

Office Action at pp. 4-5.

Wilson is directed to a stent delivery catheter for delivering and implanting a stent at or near an area of septal perforations. The delivered stents have openings that correspond to septal perforations to prevent covering of the orifices of the septal perforation when the stent is expanded. The delivery catheter includes an opening (145) in the side wall that is aligned with an opening or openings in the stent. In use, a guide wire (151) is moved from within the catheter, through the opening (145) in the catheter, through the opening in the stent, and into a septal perforation (7). Placement of the guide wire (151) in the septal opening (7) permits alignment of the opening in the

stent (20) with the septal perforation (7). FIG. 18 of Wilson, reproduced below, illustrates this concept.

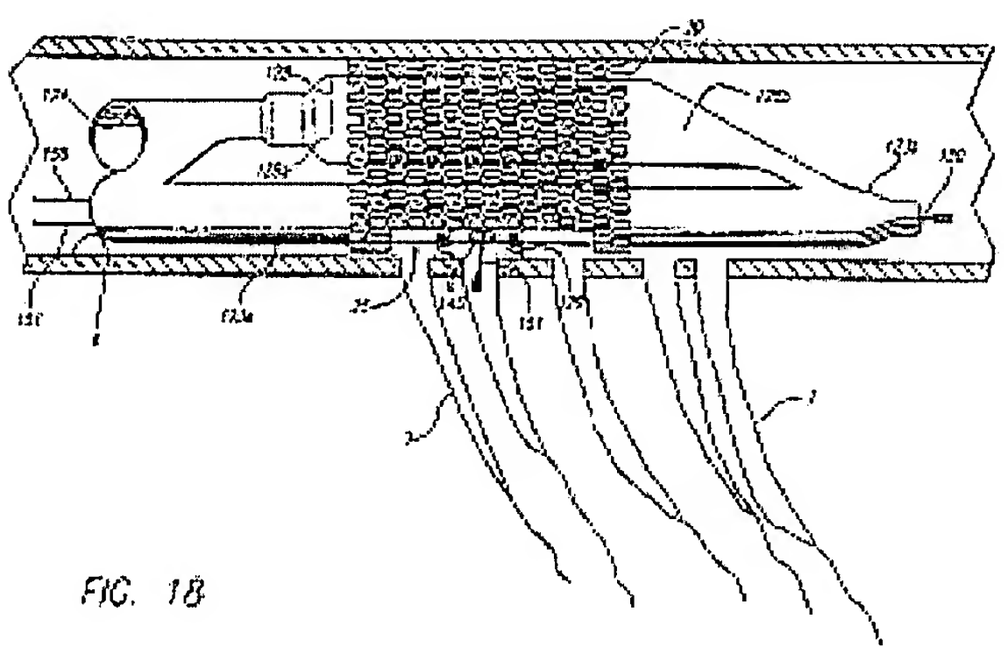

FIG. 18

Because Wilson uses an opening in the sidewall of the catheter to pass a guide wire into a septal perforation, use of an outer catheter would destroy the utility of Wilson's system. Placing an outer catheter around the catheter of Wilson would prevent Wilson's guide wire from entering a septal perforation. The guide wire permits alignment of Wilson's stent with the septal perforations, and appears critical to the operation of Wilson's system. Thus, the use of an outer catheter is at odds with Wilson's stent delivery system and it would be inappropriate to add an outer catheter to the Wilson system based on the disclosure of Phelps.

The Haarstad reference was cited to teach that "it is well known in the art to use a stiff guidewire to penetrate lesions," a concept not found in the Wilson reference. However, the Haarstad reference does not remedy the deficiencies of the Wilson or Phelps references as discussed above. In particular, Haarstad does not suggest or disclose an outer catheter that could be added to Wilson's stent delivery system.

Accordingly, the rejection of claims 24, 25, 27, 30, 33, and 34 over Wilson in view of Haarstad and Phelps cannot stand.

Conclusion

In consideration of the forgoing remarks, Applicants respectfully requests reconsideration of this application and allowance of the pending claims. Should any issue remain outstanding, please feel free to contact the undersigned.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 6, 2007

By: _____
Kevin Cronin
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